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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,857	04/06/2006	Fritz Blatter	2006-0167A	5499
513 7590 06/01/2010 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER				
RAO, GNAGESH				
ART UNIT		PAPER NUMBER		
1714				
NOTIFICATION DATE		DELIVERY MODE		
06/01/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com  
coa@wenderoth.com

### Office Action Summary

**Application No.**

10/574,857

**Applicant(s)**

BLATTER ET AL.

**Examiner**

G. NAGESH RAO

**Art Unit**

1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG-08)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1) Claims 1,3,7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims uses the term “substantially” to pertain with the amorphous organic compound, be it crystallized or not, but in an unclear manner. Are the compounds fully amorphous or partially? The term substantially is attempting to indicate that the material is amorphous but attempting to create leeway as to not being fully amorphous resulting in an unclear manner, as to what the claimed invention is directed too. With the limitation currently presented it reads as a potential option but not further elaborated as to what it is definitively. Correction and clarification is solicited.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2) Claims 1-2 and 6-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Stahly (US Patent No. 6,750,064).

Examiner points out that independent claim 1 is written in a Jepson format (See MPEP 2129) indicates an implied admission that the subject matter of the preamble is the prior art work of another. Therefore it is not considered to have patentable weight with respect to the novel improvement that follows thereafter.

Stahly 064 clearly discloses a mostly amorphous crystallizing organic based compound in a mixture of at least two organic compounds which may be used as a solution and thus resulting in a saturated solution (See Col 2 Lines 4-55, Col 4 Lines 48-52, Col 6 Lines 9-34, and examples 1-3).

Furthermore Stahly 064 discloses a process that allows for spectroscopic detection of the compound to occur in what would be understood as a pipet and substrate tray arrangement which would also allow for agitation of the mixture within the tray to occur (See Cols 7-8 Lines 1-69).

With respect to the limitation on the characterization of the term “substantially amorphous” the clause “may” indicates it is an optional limitation and does not necessarily indicate that it must contain crystalline phases.

3) Claims 1-4 and 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hilfiker et al “Polymorphism-Integrated Approach From High-Throughput Screening to Crystallization Optimization”.

Hilfiker et al clearly discloses a mostly amorphous crystallizing organic based compound in a mixture of at least two organic compounds which may be used as a solution and thus resulting in a saturated solution existing at more than 80% excess by weight in the mixture (See Pp 429-440).

Furthermore Hilfiker et al discloses a process that allows for spectroscopic detection of the compound to occur in what would be understood as a pipet and substrate tray arrangement which would also allow for agitation of the mixture within the tray to occur (See Pp 429-440).

With respect to the limitation on the characterization of the term “substantially amorphous” the clause “may” indicates it is an optional limitation and does not necessarily indicate that it must contain crystalline phases.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hilfiker et al “Polymorphism-Integrated Approach From High-Throughput Screening to Crystallization Optimization”.

Hilfiker et al fail to disclose the excess is in at least 100% by weight with respect to the process of claim 1. This limitation is viewed as being resultant effective variable and would be obvious to one having ordinary skill in the art at the time of the invention to ascertain via routine experimentation.

5) Claims 3-5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahly (US Patent No. 6,750,064).

Stahly 064 fail to disclose the excess is in at least 30%, 50%, or 100% by weight with respect to the process of claim 1. These limitations are viewed as being resultant effective variable and would be obvious to one having ordinary skill in the art at the time of the invention to ascertain via routine experimentation.

### ***Response to Arguments***

6) Upon review of the filed amendment, examiner has agreed to withdraw drawing objections.

However the limitations put forth do not further limit the claimed invention, with respect to claims 1 and 11, the word “may” as used in the claim denotes an option and not a required feature, therefore the substantially amorphous limitation only defines an example but does not definitively define the value appropriately. The arguments presented regarding the gibbs free energy and methodology of processing are not commensurate in scope with the presently claimed invention. Applicants are essentially arguing limitation interpretations and language from the specification but not necessarily denoted in the claimed invention itself.

Further examiner points out that claim 10 which is directed to an apparatus is only having to be capable not required to perform the process steps amended into the preamble. See MPEP 2115 R-2.

At this time examiner can not concur that the claimed invention has met the conditions for patentability.

### ***Conclusion***

7) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to G. NAGESH RAO whose telephone number is (571)272-2946. The examiner can normally be reached on 8:30AM-5PM (INDEPENDENT FLEX SCHEDULE).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael KORNAKOV can be reached on (571)272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. Nagesh Rao/  
GAU-1714  
Patent Examiner

